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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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30223	7590	12/16/2004	EXAMINER	
JENKENS & GILCHRIST, P.C. 225 WEST WASHINGTON SUITE 2600 CHICAGO, IL 60606			MADSEN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/915,150	Applicant(s) DELDUCA ET AL.	
	Examiner Robert Madsen	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37,87-90 and 161-171 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37,87-90,161-171 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed September 13, 2004 has been entered. Claims 1-37 and 87-189 remain pending.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-6,8-11,13-26,28-30,32-37,87-90,161,162,164-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (US 6054153) in view of Koch et al. (US 3459117) and Woodruff et al. (US 4522835) and Shaklai (US 6042859)
4. Carr et al. teach a method of manufacturing a modified atmosphere meat package comprising a first package made of a polystyrene foam tray sealed by a permeable pvc overwrap as recited in claims 16,17 and 35, covering the first package with a second impermeable package such that a pocket is formed between the two packages, flushing the pocket ,as recited in claims 8,28,164 with gases consisting essentially of about 30% carbon dioxide and about 70% nitrogen, as recited in claims 9-11,29,30 in order to lower the level of oxygen in the pocket to preferably less than 0.5%, as recited in claims 5 , 6,25,26,165,166 to prevent the formation of metmyoglobin, as recited in claims 1,22, and 161. Additionally, Carr et al. teach flushing alone may not reduce the level of oxygen to less than 0.5%, which would be evident by the formation of oxymyoglobin as

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recited in claim 22, and teach placing an oxygen scavenger and accelerator in the pocket to reduce the level about zero percent in less than 24 hours, as recited in claims 2-4,23,24,162. Carr et al. further teach removing the second package, which would modify the packages atmospheres and would not destroy the first package, before retailing to allow the raw meat to be exposed to ambient atmosphere to give the meat the same color as fresh meat as recited in claims 13-15,32-34,87-90,167-171 (Abstract, Column 1, line 46 to Column 2, line 45,Column 3, lines 47-67,Column 5, line 60 to Column 6, line 49).

5. However, Carr et al. are silent in teaching 0.1-0.8%,0.3-0.5% , or 0.1-0.5%, carbon monoxide in addition to the carbon dioxide and nitrogen to form carboxymyoglobin, as recited in claims 1, 11, 18-21,30,36,37,161 or convert deoxymyoglobin directly to carboxymyoglobin as recited in claim 1 or oxymyoglobin to carboxymyoglobin as recited in claim 22, wherein the CO is associated with the raw meat within the first package is adapted to be removable, as recited in claims 1,22, and 161.

6. Koch et al., like Carr et al., are concerned with providing a red-colored meat at the retail outlet. Koch et al. teach a bright red color is needed to make meat attractive for sale, and teach a method of artificially extending the red color when the meat is at the retail outlet. Koch et al. teach wrapping a meat with CO containing film under a modified atmosphere, so that the carbon CO is transferred from the film to contact the surface of the meat so that carboxymyoglobin is formed on the meat surface(Column 1, lines 23-50, Column 2, line 67 to Column 3, line3, Column 3, line 49 to column 4,line 10). Koch et al.

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teach the meat will remain a "saleable" red color for as long as 10 days when the modified atmosphere package remains in contact with the meat for 7 days , and the modified atmosphere CO-containing package is removed from contact with the meat for 3 days (replaced by a conventional wrapper) at the retail outlet (Column 3, lines 4-16). Additionally, Koch et al. are relied on as evidence that CO is removably associated with a meat surface since the color is "fixed" for only a finite time after the CO-containing wrapper is removed.

7. Woodruff et al. also teach treating meat in a modified atmosphere to convert deoxymyoglobin to carboxymyoglobin on the surface of the meat, but further teach CO is supplied as a gas to contact the surface of the meat wherein the gas mixture comprises 0.1-3% CO, along with 20-60% CO₂ , 40-80% N₂ , and 0% O₂ . Woodruff et al. further teach only the first 0.25 inch of the meat are affected by the CO. Woodruff et al. also teach the meat is stored in these conditions prior to final sale/consumption packaging. Woodruff et al. teach removing the O₂ causes the meat to turn purple, while carbon monoxide will provide a desirable red color during storage, or the same color as fresh meat (Abstract, Column 1, line 63 to Column 3, line 30, Examples).

8. Therefore, it would have been obvious to modify Carr et al. and include anywhere from 0.1-0.8% carbon monoxide , 40-80% nitrogen, and 20-60% carbon dioxide in the modified atmosphere pocket (i.e. between the two packages) to convert the deoxymyoglobin to carboxymyoglobin as recited in claims 1,11,18-22,30, 36, 37 and 161, since Koch et al. teach storing meat in a modified atmosphere with CO to contact the surface of the meat will provide an

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extended time period wherein the meat remains red at the retail outlet after removal from a modified atmosphere package with CO and Woodruff et al. teach low/no oxygen modified atmosphere including CO in gas form that contacts the surface of the meat (i.e. affects the first 0.25 in.) to turn the meat a red color comprises 0.1-0.8% carbon monoxide along with 40-80% nitrogen and 20-60% carbon dioxide. One would have been substituting one conventional carbon dioxide/ nitrogen based atmosphere for another for the same purpose: providing a low/no oxygen atmosphere for providing the appearance of fresh cut meat after storage. Forming carboxymyoglobin from deoxymyoglobin or oxymyoglobin would have been an obvious result effective variable of the level of oxygen in the modified atmosphere since Carr et al. teach some oxygen may or may not be present during the first 24 hours.

9. Shaklai is relied on as further evidence that upon exposure to air, or removal of the first package as taught by Carr et al., CO is removable. Shaklai teaches storing meat in a 100% CO environment. Shaklai teaches the entire meat becomes red, but after removing the meat from the CO enriched environment and exposing the meat to room atmosphere the outer 1mm eventually becomes brown in 14 days (Example 4 in light of Example 3 in Column 9). Thus, the CO is removable from the surface (or <1mm) of CO treated meat (i.e. loss of red color) when exposed to room air. Carr et al. teach the meat held under modified atmosphere will be exposed to room air at the time of retail, Koch et al. teach meat surfaces treated with CO in an modified atmosphere package will only remain red for a finite period upon removal from the modified

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atmosphere package, and Woodruff et al. teach the modified atmosphere of 0.1-3% CO will affect the color of the meat to only the depth of 0.25 inch. Thus, in light of Shaklai., one would expect the CO associated with the meat to be removable in the package of Carr et al. , since meat will lose the red color to depth of 1 mm when removed from exposure to CO and exposed to air.

10. Claims 1,2,5-10,12-15,18-23,25-29,31-34,36,37,87-90,161-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breen et al. (US 5711978) in view of Koch et al. (US 3459117) and Woodruff et al. (US 4522835) and Verbruggen (DE 1935566 A) and Shaklai (US 6042859)

11. Breen et al. teach a method of packaging meat in a modified atmosphere package for sale/consumption comprising supplying a first package comprising a sealed tray, surrounding the tray with a bag, removing oxygen by vacuum , supplying/flushing the bag, as recited in claims 7,8,27,28,163,164 with substantially pure carbon dioxide gas, as recited in claims 9,10,12,28,29, 31,165,166, and sealing the bag such that oxygen is at 30-50 ppm in the pocket, equilibrating within minutes to 250 ppm and eventually drops off significantly as the meat absorbs the oxygen, as recited in claims 5,6,25,26, which would in turn form oxymyoglobin as recited in claims 18, 22 prevent the formation of metmyoglobin, as recited in claims 1,22, and 161, and due to the lack of oxygen in the package result in the formation of deoxymyoglobin as recited in claims 19 Additionally, Breen et al. teach at least a portion of bag can be removed for retailing without destroying the tray to expose the meat to ambient atmosphere,

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as recited in claims 13-15,32-34,87-90,167-171, As an extra measure of safety, Breen et al. further teach adding an oxygen scavenger in the pocket, as recited in claims 2,23,162(Figure 7, Column 2, lines 27-62, Column 4, lines 40-63, Column 5, line 5 to Column 6, line 5). However, Breen et al. are silent in teaching 0.1-0.8%,0.3-0.5% , or 0.1-0.5%, carbon monoxide in addition to the substantially pure carbon dioxide, as recited in claims 1, 12,18-22,31,36,37,161 or convert deoxymyoglobin directly to carboxymyoglobin as recited in claim 1 or oxy myoglobin to carboxymyoglobin as recited in claim 22, wherein the CO is associated with the raw meat within the first package is adapted to be removable, as recited in claims 1,22, and 161.

12. Koch et al., like Breen et al., are concerned with providing a red-colored meat at the retail outlet. Koch et al. teach a bright red color is needed to make meat attractive for sale, and teach a method of artificially extending the red color when the meat is at the retail outlet. Koch et al. teach wrapping a meat with CO containing film under a modified atmosphere, so that the carbon CO is transferred from the film to contact the surface of the meat so that carboxymyoglobin is formed on the meat surface(Column 1, lines 23-50, Column 2, line 67 to Column 3, line3, Column 3, line 49 to column 4,line 10). Koch et al. teach the meat will remain a "saleable" red color for as long as 10 days when the modified atmosphere package remains in contact with the meat for 7 days , and the modified atmosphere CO-containing package is removed from contact with the meat for 3 days (replaced by a conventional wrapper) at the retail outlet (Column 3, lines 4-16). Additionally, Koch et al. are relied on as evidence that

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CO is removably associated with a meat surface since the color is "fixed" for only a finite time after the CO-containing wrapper is removed.

13. Woodruff et al. also teach treating meat in a modified atmosphere to convert deoxymyoglobin to carboxymyoglobin on the surface of the meat, but further teach CO is supplied as a gas to contact the surface of the meat wherein the gas mixture comprises 0.1-3% CO, along with 20-60% CO₂, 40-80% N₂, and 0% O₂. Woodruff et al. further teach only the first 0.25 inch of the meat are affected by the CO. Woodruff et al. also teach the meat is stored in these conditions prior to final sale/consumption packaging. Woodruff et al. teach removing the O₂ causes the meat to turn purple, while carbon monoxide will provide a desirable red color during storage, or the same color as fresh meat (Abstract, Column 1, line 63 to Column 3, line 30, Examples).

14. Verbruggen is relied on as further evidence of the conventionality of utilizing a carbon dioxide and carbon monoxide gas mixture for preserving meat (See Abstract).

15. Therefore, it would have been obvious to modify Breen et al. and include anywhere from 0.1-0.8% carbon monoxide, 40-80% nitrogen, and 20-60% carbon dioxide in the modified atmosphere pocket (i.e. between the two packages) to convert the deoxymyoglobin to carboxymyoglobin as recited in claims 1,11,18-22,30, 36, 37 and 161, since Koch et al. teach storing meat in a modified atmosphere with CO to contact the surface of the meat will provide an extended time period wherein the meat remains red at the retail outlet after removal from a modified atmosphere package with CO and Woodruff et al. teach

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low/no oxygen modified atmosphere including CO in gas form that contacts the surface of the meat (i.e. affects the first 0.25 in.) to turn the meat a red color comprises 0.1-0.8% carbon monoxide along with 40-80% nitrogen and 20-60% carbon dioxide. One would have been substituting one conventional carbon dioxide/ nitrogen based atmosphere for another for the same purpose: providing a low/no oxygen atmosphere for providing the appearance of fresh cut meat after storage. Forming carboxymyoglobin from deoxymyoglobin or oxymyoglobin would have been an obvious result effective variable of the level of oxygen in the modified atmosphere since Breen et al. teach some oxygen may or may not be present during the first 24 hours.

16. Shaklai is relied on as further evidence that upon exposure to air, or removal of the first package as taught by Breen et al., CO is removable. Shaklai teaches storing meat in a 100% CO environment. Shaklai teaches the entire meat becomes red, but after removing the meat from the CO enriched environment and exposing the meat to room atmosphere the outer 1mm eventually becomes brown in 14 days (Example 4 in light of Example 3 in Column 9). Thus, the CO is removable from the surface (or <1mm) of CO treated meat (i.e. loss of red color) when exposed to room air. Breen et al. teach the meat held under modified atmosphere will be exposed to room air at the time of retail, Koch et al. teach meat surfaces treated with CO in an modified atmosphere package will only remain red for a finite period upon removal from the modified atmosphere package, and Woodruff et al. teach the modified atmosphere of 0.1-3% CO will affect the color of the meat to only the depth of

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0.25 inch. Thus, in light of Shaklai., one would expect the CO associated with the meat to be removable in the package of Breen et al. , since meat will lose the red color to depth of 1 mm when removed from exposure to CO and exposed to air.

Response to Amendment

17. The Declaration under 37 CFR 1.132 filed June 21, 2004 by Dr. Melvin C. Hunt and the Declaration under 37 CFR 1.132 filed June 21, 2004 by Mr. Gary DelDuca are insufficient to overcome the rejection of claims because the Declarations states the prior art considered CO to "fix" the color. The prior art does teach meat turns red, or carboxymyoglobin is formed, but as now presented in the rejected claims set forth above, the prior art *does* acknowledge that CO is removably associated, at least to a depth of 1mm. As stated in the rejections above, Shaklai teaches meat that is completely saturated with CO does not have a fixed color. In fact, after exposing CO to air for 14 days the surface (or <1mm deep) of the meat turns brown. Koch et al. teach only exposing the surface of a meat to CO to provide a red color by encasing the meat in a CO-containing wrapper. Koch et al. teach the red color is maintained for 10 days: 7 days in contact with CO-containing wrapper, followed by 3 days without contact with CO. Thus, the two references cited (e.g. Shaklai and Koch et al.) teach the meat browns as expected in a normal atmosphere within days after being stored within in either a high level or low level CO-environment. One would expect that at the levels taught by Woodruff , 0.1-3% CO, and the depth of

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CO saturation taught by Woodruff, 0.25 in (i.e. less than 1mm) that the CO would be removable from surface, since even a CO saturated piece of meat will lose its red surface after 14 days exposure to room air. Thus, one would expect that the packages of Carr et al. or Been et al., which store meat in a modified atmosphere with the intention of exposing the meat to room air for several days, would provide allow the CO to be removable when the meat is exposed to room air. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

18. Applicant's arguments with respect to the rejections have been fully considered but they are not persuasive.

19. Applicant argues that the present invention does not "fix" the color, and the prior art cited in the previous office action does not provide motivation to modify either Carr et al. or Breen et al. because one of ordinary skill in the art would have recognized that the combination would generate a "fixed" color. However, as discussed in the present rejections, the prior art teaches that CO, while changing the color of a meat red, will not "fix" the surface layer of the meat, even when the meat has been saturated with CO. In fact, the prior art presently cited, if anything, teaches fixing is an obvious result effective variable of the level of CO to which the meat is exposed. As presently rejected, Koch et al. provide motivation for allowing CO to contact a meat surface while the meat is stored in a modified atmosphere package: to extend the red color of the meat at the retail

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outlet. Additionally in one example, Koch et al. teach that after the meat is no longer in contact with the CO supplying environment, the meat will only remain "fixed" for three days. Woodruff et al. teach how to create a red color meat surface in a modified atmosphere using CO as part of the modified atmosphere such that only 1mm will change in color (i.e. using 0.1-3% CO). Shaklai teaches, after 14 days exposure to air, even a CO-saturated meat will lose its red-coloring in the first 1mm from the meat surface. Thus, in light of Koch et al. and Shaklai, one would not expect the packaging method of Carr et al. or Breen et al. with the modified atmosphere of Woodruff et al would adversely "fix" the color of the meat upon removal of the first package.

20. Applicant further argues that Breen et al. teach substantially pure carbon dioxide, and it would not have been obvious to add any additional gas to the modified atmosphere. However, "substantially pure" does not exclude any other gas, especially at 0.1-0.8%. Furthermore Verbaggen teaches it is known to include carbon dioxide and carbon monoxide to preserve meat.

21. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Carr et al. and Breen et al. teach packaging

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methods to package a meat in a modified atmosphere wherein the meat is exposed to room air to provide a red color at the retail outlet. Koch et al. teach how to extend the red color meat when the meat is removed from a modified atmosphere package by providing CO removable associating with the meat surface. Shaklai teaches even meat exposed to saturated CO gas, will have CO removably associated with the surface. Thus one would expect that the modified atmosphere taught by Woodruff et al. that provides the surface of the meat with a red color at a level of 0.1-3.0% CO, would not only meet the requirements of Carr et al. and Breen et al. (i.e. provide a red color of the room air exposed meat at retail), but extend the red color for a finite period of time.

22. Applicant further argues that Applicant is the first to have FDA approved CO-containing meat packages, as noted above the art recognized storing meat in a modified atmosphere package wherein the meat surface is exposed to CO and the CO is removable from the surface of the meat once the modified atmosphere is removed. Considering the prior art as whole, the fact that FDA had not approved the use of CO is not relevant to the issue of obviousness in this case. Patent law is independent from FDA regulatory law. This issue often is discussed with respect to the determination of pharmaceutical utility (MPEP 2107.01: Section V.):

"FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing Scott v. Finney, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994)).

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23. With respect to the present invention meeting a long-felt need, establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. In re Gershon, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967). It is notoriously well known in the art, as discussed in the various references cited, that a red colored meat at the retail outlet is most desired. It was also known that meat exposed to CO in a modified atmosphere environment would provide the meat with a red color after the meat was removed from the modified atmosphere environment.

24. With respect to the commercial success, it is not clear if the claimed invention resulted in the commercial success or whether other factors contributed to the success, such as increase advertising/marketing. " In considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention, etc. "(In re Mageli, 470 F.2d 1380, 176 USPQ 305 (CCPA 1973)).

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

26. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (571) 272-1402. The examiner can normally be reached on 7:00AM-3:30PM M-F.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 1761

